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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,824	05/14/2001	Kristin J. Godbey	56466USA.002	9149

32692 7590 07/02/2003

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EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,824

Applicant(s)

GODBEY ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Examiner acknowledges receipt of IDS, three months extension of time and Amendment A filed on 4/1/03.

The 112 (first paragraph) rejection for claims 5,9,13,38 have been overcome and is considered withdrawn.

Claims 40-50 have been cancelled.

Claims 1-39 are pending.

Specification

The abstract of the disclosure is objected to because of the inclusion of the word "said". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

Claims 1,15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 15, the term "generally" is a relative term which renders the claim indefinite. The term "generally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (U.S. Patent No. 5,688,523) in view of Scholz et al. (U.S. Patent No. 6,019,997).

Garbe teaches a pressure sensitive skin adhesive sheet material comprising a liquid and a base layer which comprises a polymer (col.2, lines 53-66). Garbe teaches that the adhesive sheet comprises a water-soluble carrier comprising addition polymers (e.g. acrylates) (col.3, lines 4-10) and liquid excipients which include polyethylene glycol, polyethylene oxide and propylene glycol which can read on plasticizers (col.4, lines 47-63). Garbe discloses a backing film (col.3, lines 31-40).

Garbe does not teach an active agent.

However, Scholz teaches hydroalcoholic compositions comprising pharmaceutical active agents (i.e. antibacterials, steroids) (col.16, lines 44-67, bridging col.17, lines 1-27) which are known for treating skin conditions. Scholz teaches that the compositions can be used in transdermal delivery systems (e.g. devices) and can be placed within a polymeric material such as an adhesive (col.17, lines 28-67, col.18, lines 1-5).

One having ordinary skill in the art would have been motivated to modify the composition of Garbe to include an active agent, because Scholz teaches compositions comprising active agents which can be used in transdermal devices and an adhesive.

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The expected result would be a device for delivering an active agent to a localized body surface comprising a water-soluble carrier comprising a polymer and a plasticizer, a water-soluble adhesive and a support layer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Garbe in the manner taught by Scholz.

Response to Arguments

Applicant's arguments filed 4/1/03 have been fully considered but they are not persuasive. Applicant argues that Garbe ('523) does not teach water-solubility of the polymers or the pressure sensitive adhesive. Garbe discloses neither the water-soluble/water-dispersible carrier nor the water-soluble/water-dispersible adhesive. The patent does not teach or suggest a combination of layers, each layer capable of dissolving or dispersing once in contact with water. Garbe lacks any discussion of the water-solubility of the polymer layers or the pressure sensitive sheet formed after constructing the layers together. The cited reference teaches away from water-solubility in a drug delivery device. Scholz fails to cure the deficiencies of Garbe. Scholz fails to teach or disclose a water soluble/water dispersible carrier layer or a water soluble/water dispersible adhesive layer, and only discloses use of the hydroalcoholic composition with transdermal delivery devices known in the art. There is no teaching or suggestion in Scholz that the hydroalcoholic compositions disclosed therein would be soluble in the polymers of Garbe for coating on a substrate. Thus, the combination of Garbe and Scholz fails to teach all elements of the present invention.

In response to applicant's arguments, Garbe teaches the same polymers as those of applicant's claimed invention, and the water-solubility of the polymers is an inherent quality which is encompassed by those properties. Garbe teaches a pressure sensitive skin adhesive sheet material (see col.2, lines 53-66) comprising a water-soluble carrier and addition polymers (e.g. acrylates) (see col.3, lines 4-10). The patent does teach a combination of layers, Garbe teaches a liquid, a base layer which comprises a first polymer (see col.2, lines 53-64), a second polymer (e.g. an acrylate or a styrene block copolymer (col.5, lines 6-35). Garbe also teaches a backing film (col.3, lines 31-40).

As for the argument that Scholz does not teach a water soluble carrier or adhesive layer, and that there is no teaching in Scholz that the hydroalcoholic compositions taught by Scholz would be soluble in the polymers of Garbe for coating on a substrate, there is a motivation for combining Garbe and Scholz. The motivation for combining the references is that, Garbe teaches a pressure sensitive skin adhesive sheet comprising a water-soluble carrier and addition acrylate polymers (see col.3, lines 4-10). Scholz teaches polymers which are inclusive of the generic claim 1. The claims are read for their broadest interpretation. Scholz teaches compositions which can be used in transdelivery devices (i.e. a patch), and Scholz teaches similar polymers for drug delivery to the skin.

In conclusion, the "comprising" language in the generic claim permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts. (See *Moleculon Research Corporation v CBS, Inc* 229 USPQ 805; *In re Baxter* 210 USPQ 795, 803).

The amendment does not overcome the prior art of record. The rejection set forth above is maintained for reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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746-3121 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Sharon Howard
June 26, 2003



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500